UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel.*, Deborah Conrad **Relator,** **vs.** **ROCHESTER REGIONAL HEALTH, et al.** **Defendants.**	)	**CASE NO.: 1:23-cv-00438-JLS** **JUDGE: HON. JOHN L. SINATRA, JR.**

RELATOR'S RESPONSE TO DEFENDANTS' MOTION TO DISMISS

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I. INTRODUCTION

Defendants' Motion to Dismiss rests on a flawed premise: that their obligations to report vaccine adverse events extended only to reactions occurring within 15 minutes at their vaccination sites. This interpretation contradicts the plain language of the Covid-19 Vaccination Provider Agreement, undermines the national vaccine safety monitoring system, and ignores clear allegations of systematic fraud in the Amended Complaint.

Relator Deborah Conrad, a Physician Assistant at United Memorial Medical Center/Rochester Regional Health from 2007 to 2021, alleged Defendants knowingly violated the False Claims Act by certifying compliance with mandatory adverse event reporting requirements while systematically suppressing such reporting. Among other things, the Amended Complaint details how Defendants: 1) Failed to report over 170 qualifying adverse events while continuing to claim federal funds for vaccine administration; 2) blocked healthcare providers from reporting adverse events to VAERS; 3) retaliated against Conrad when she tried to ensure proper reporting; 4) deliberately concealed evidence of adverse events; 4) and made knowing false certifications to maintain their flow of federal payments.

A. STATUTORY AND REGULATORY BACKGROUND

The National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34) was signed into law by President Reagan on November 14, 1986. It was designed "…to achieve optimal prevention of human infectious diseases through immunization and to achieve **optimal prevention against adverse reactions** to vaccines." 42 U.S.C. § 300aa-1. It limited the financial liability of vaccine manufacturers for vaccine injury claims to ensure a stable vaccine supply and to provide cost-effective arbitration for vaccine injury claims. The grant of immunity disincentivized companies to make vaccines safer so Congress obliged healthcare providers to

report certain adverse events following vaccination to a surveillance system called the Vaccine Adverse Event Reporting System (VAERS).[1] These reports alert the CDC and FDA to health problems potentially caused by vaccines. Doc. 34, ¶¶ 19-21.

The VAERS system also tracks injuries for emergency use authorized (EUA) drugs and vaccines because these products have not completed standard safety and efficacy testing. Congress mandated the Secretary of Health and Human Services to protect public health by establishing compulsory safety monitoring requirements. On February 4, 2020, the Secretary of Health and Human Services determined Covid-19 was a public health emergency that could affect national security and the health of United States citizens. This determination enabled EUAs for Covid-19 vaccines and, in December 2020, the Secretary authorized the use of **unapproved** Covid-19 vaccines.

The Secretary then set mandatory reporting obligations for Covid-19 vaccination providers. The FDA stated in the Federal Register that, "While Covid-19 vaccines are being used under an EUA, vaccination providers, manufacturers, and EUA sponsors must, in accordance with the National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. 300aa–1 to 300aa–34), report select adverse events to VAERS (that is, serious adverse events, cases of multisystem inflammatory syndrome (MIS), and COVID–19 cases that result in hospitalization or death)." 86 Fed. Reg. 26,311 (May 13, 2021). On the next page, it was emphasized that "FDA is closely monitoring the safety of the COVID–19 vaccines authorized for emergency use. The vaccination provider is responsible for mandatory reporting to VAERS of certain adverse events as listed on the Health Care Provider Fact Sheet." 86 Fed. Reg. 26,312 (May 13, 2021).

[1] https://www.vaers.hhs.gov

The Covid-19 vaccine EUAs listed mandatory VAERS reporting requirements for vaccine providers like Defendants:

> a. Vaccine administration errors whether or not associated with an adverse event.
> b. Serious adverse events (irrespective of attribution to vaccination).
> c. Cases of Multisystem Inflammatory Syndrome in children and adults.
> d. Cases of COVID-19 that result in hospitalization or death."[2]

"Serious adverse events" "regardless of whether the reporter thinks the vaccine caused the [adverse event]" are defined by the FDA to include:

1. Death;
2. A life-threatening adverse event;
3. Inpatient hospitalization or prolongation of existing hospitalization;
4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
5. A congenital anomaly/birth defect;
6. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.[3]

The EUA statute, 21 U.S.C. § 360bbb-3 has ongoing safety monitoring obligations beyond vaccine administration including: 1) adverse event reporting during the emergency declaration period unless specifically revoked by the Secretary of Health and Human Services. 21 U.S.C. § 360bbb-3(e)(1)(A) & (g)(2); 2) periodic review of the circumstances and appropriateness of the authorization, including safety data so the Secretary can assess whether "circumstances make such revision or revocation appropriate to protect the public health or safety." 21 U.S.C. § 360bbb-3(g)(2)(C); and 3) after the emergency declaration ends or authorization is revoked, the statute

[2] Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization reissued 05-10-2021 (fda.gov) (Pfizer); Moderna COVID-19 Vaccine EUA Letter of Authorization 10122022 (fda.gov) (Moderna), Janssen Letter Granting EUA Amendment (May 5, 2022) (fda.gov) (Johnson & Johnson).

[3] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html (accessed 5-2023); the page has since been changed to add additional events and is at https://vaers.hhs.gov/reportevent.html (accessed 1-31-2025) These requirements are cited in Exhibit A of Defendants' Motion to Dismiss at Doc. 38-1, p. 6.

mandates continued monitoring of patients who received the vaccine during the authorization period, as necessary for patient care. 21 U.S.C. § 360bbb-3(f)(2).

To participate in the CDC's Covid-19 Vaccination Program, receive vaccine doses, and obtain reimbursement for vaccine administration, providers like the Defendants must execute a Provider Agreement. Doc. 34, ¶ 40; Doc. 34-24. The Provider Agreement expanded the statutory reporting obligation, explicitly mandating as an "Agreement Requirement" that the "Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS)." Id. The Provider Agreement elevated this reporting duty to a "material condition of payment" for healthcare providers administering Covid-19 vaccines, linked VAERS reporting compliance with the right to receive federal funds for vaccine administration, and provided criminal and civil penalties for violations.

The Provider Agreement states:

> By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true.
>
> The above requirements are **material conditions of payment** for COVID-19 Vaccine-administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare and Medicaid, or submitted to any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare program if Organization fails to comply with these requirements with respect to the administered COVID-19 Vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose.
>
> Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and **criminal and civil penalties** under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349. Id.

The scope of reportable events underscores that providers must not narrowly limit reporting based on clinical judgment or proximity to vaccine administration. Rather, the statute, the Provider Agreement, and the guidance mandate robust reporting to monitor vaccine safety. As shown below, Defendants knowingly and systematically failed to meet these obligations while continuing to claim government funds for vaccine administration.

B. DEFENDANTS' SYSTEMATIC SUPPRESSION OF VAERS REPORTING SHOWS CONSCIOUS NON-COMPLIANCE AT AN ORGANIZATIONAL LEVEL

Relator Conrad observed many serious adverse events in patients following COVID-19 vaccinations. Doc. 34, ¶ 53. Recognizing these events were not being reported to VAERS as required, Conrad began submitting VAERS reports in March 2021. Id., ¶ 55. Her efforts to ensure proper reporting were subsequently systematically suppressed by the Defendants.

Defendants made a coordinated effort to suppress mandatory reporting to VAERS violating their obligations under the Provider Agreement and other applicable laws and regulations. This systematic suppression is shown by these actions:

1. Institutional Failure to Educate: Defendants deliberately did not educate their staff about VAERS reporting requirements. Doc. 34, ¶¶ 57-58. Hospital leadership, particularly UMH President Dan Ireland, falsely stated that the organization had no duty to educate providers about VAERS reporting. Doc. 34, ¶ 114.
2. Directive to Limit Reporting: Hospital leadership, including Dr. Gellasch and UMH President Dan Ireland, issued directives to restrict VAERS reporting. They told Relator Conrad to "dial it back" and instructed her to only report on patients under her direct care. Doc. 34, ¶¶ 68-69, 72.
3. Active Interference with Reporting Efforts: When Relator Conrad tried to fulfill her mandatory reporting requirements, the defendants actively interfered. They audited her

submissions, labeled her efforts as "overreporting," and restricted her ability to report. Doc. 34, ¶¶ 53-74.

4. Intimidation of Staff: defendants employed intimidation tactics to discourage reporting. By labeling Conrad an "anti-vaxxer," telling her to "tow the company line", and firing her, management discouraged reporting throughout the organization. Doc. 34, ¶¶ 70-71.
5. Concealment of Vaccine-Related Information: In at least one case (patient S.C.), the Defendants removed vaccine related information from the discharge summary and death certificate. Doc. 34, ¶ 87.
6. Failure to Act on Identified Cases: When specific cases requiring VAERS reports were brought to Defendants' attention, including eleven breakthrough COVID-19 cases and six other patients, they failed to ensure these reports were filed. Doc. 34, ¶¶ 77-78.
7. Retaliation Against Whistleblowers: Defendants retaliated against staff who insisted on meeting reporting requirements. Relator Conrad was interrogated, threatened with professional sanctions, and ultimately escorted out of the hospital in a humiliating way. FAC, Doc. 34, ¶ 90 and ¶ 94.
8. Systemic Underreporting: Defendants' actions led to widespread underreporting. At least 170 patients had adverse events blocked from being reported to VAERS. Doc. 34, ¶ 92.
9. Disruption of Communication: Conrad, helped by Dr. Danielle Notebaert, UMMC Lead Emergency Room Physician, identified ER patients who needed VAERS reports or who were potentially having adverse side effects from their vaccines. Doc. 34, ¶ 112. Conrad was later barred from communicating with Dr. Notebaert. Id, ¶ 56.

These actions show Defendants exercised control over healthcare providers and staff and stopped reporting efforts ensuring non-compliance with mandatory VAERS reporting

requirements. This systematic suppression was a deliberate strategy, implemented by management, to avoid legal and ethical duties under the Provider Agreement, applicable laws, and regulations.

II. LAW AND ARGUMENT

A. LEGAL STANDARDS

Federal Rule of Civil Procedure 12(b)(6) provides that a complaint may be dismissed for failure to state a claim upon which relief can be granted. Fed. R. Civ. Proc. 12(b)(6). In evaluating a motion to dismiss under Rule 12(b)(6), a court must "accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the non-movant." *Sheppard v. Beerman*, 18 F.3d 147, 150 (2d Cir.1994), citing *Ad--Hoc Comm. of Baruch Black & Hispanic Alumni Ass'n v. Bernard M. Baruch College*, 835 F.2d 980, 982 (2d Cir.1987). To defeat a motion to dismiss, "Factual allegations must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1964--65, 167 L.Ed.2d 929 (2007). In determining the motion, the Court's review is generally limited to the complaint and documents incorporated by reference. See *Savino v. Lloyds TSB Bank, PLC*, 499 F.Supp.2d 306, 310 (W.D.N.Y.2007).

The FCA was enacted to indemnify the government against losses caused by fraud. *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir.2001) (overruled on other grounds, citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 549, 551--52, 63 S.Ct. 379, 87 L.Ed. 443 (1943)). Liability is incurred where an individual: (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of [(A) or (B)]. 31 U.S.C. §§ 3729(A)(1)(A)-(C). *United States ex rel. Forcier v.*

Computer Scis. Corp., 183 F. Supp. 3d 510, 522 (S.D.N.Y. 2016). Under Section (G), an individual is liable when the individual "[...] knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government [...]." 31 U.S.C. § 3729(A)(1)(G). The FCA does not require "proof of specific intent to defraud"; rather, an individual acts knowingly where he has "actual knowledge" or "acts in deliberate ignorance ... [or] reckless disregard" regarding falsity. Id. § 3729(B).

"A successful FCA claim generally occurs in one of three forms: (1) a factually false claim; (2) a legally false claim under an express false certification theory; and (3) a legally false claim under an implied certification theory." *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 104 (2d Cir. 2021) (internal quotations omitted).

In FCA cases, Rule 9(b) requires relators to plead the circumstances constituting fraud with particularity. The particularity requirement requires relators make plausible allegations that create a strong inference that specific false claims were submitted to the government and that the information to identify those claims is peculiarly with the opposing party's knowledge. *United States ex rel. Chorches v. Am. Med. Response, Inc*., 865 F.3d 71, 86 (2d Cir. 2017).

B. RELATOR PLEADED SUFFICIENT FACTS UNDER RULE 12(B)(6) TO SHOW DEFENDANTS VIOLATED THE FALSE CLAIMS ACT

1. Submission of claims

The FAC detailed allegations showing Defendants submitted false claims for COVID-19 vaccine administration. Defendants participated in a simplified HHS process allowing providers to "submit individual claims or roster bill, without enrolling as a mass immunizer." Doc. 34 ¶ 95. While Relator did not work in billing, she confirmed claims submissions through conversations with staff and publicly available information about the federal reimbursement process.

The FAC explains that Defendants use sophisticated accounting and billing systems to track services and ensure payment. For each COVID-19 vaccine dose administered, Defendants' systems record the service in the patient's medical record, document administration in the New York State Immunization Information System (NYSIIS) and generate a claim for payment. Doc. 34 ¶ 97. Through these integrated systems, controlled by Defendants, the organization tracks every dose from administration through payment processing. While Relator lacks direct access to the billing systems, she knows the billing department processes vaccine administration records into claims seeking the standard $40 payment per dose through established federal healthcare program billing procedures, including Medicare, Medicaid and the HRSA COVID-19 Uninsured Program. Id.

The falsity of Defendants' claims stems not from irregularities in the billing process itself, but from their systematic failure to fulfill VAERS reporting obligations while certifying compliance to obtain those payments. Each time billing staff transmitted claims for vaccine administration payments, those claims implicitly certified Defendants met material conditions of the Provider Agreement - including VAERS reporting requirements. Id ¶ 98. The FAC provides a specific example through patient S.C., whose vaccine-related death went unreported while Defendants claimed payment for administering his vaccine, showing how systematic non-compliance rendered all claims false. Id ¶ 99.

This pattern of behavior meant that each claim submitted for vaccine administration payment was false because VAERS reporting was required by multiple federal authorities: the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-25), the Emergency Use Authorization statute (21 U.S.C. § 360bbb-3(e)(1)(A)(iii)), implementing regulations and FDA reporting requirements. Id ¶ 101. These obligations were material conditions of participation in the COVID-

19 Vaccination Program, reinforced by the Provider Agreement where each claim for payment expressly and implicitly certified compliance with all program requirements - compliance Defendants knowingly failed to maintain while continuing to submit claims for payment for vaccine administration. Id.

2. Relator pleaded sufficient facts to establish falsity based on defendants' knowing non-compliance with express material statutory, regulatory, and contractual requirements.

The statutory and regulatory framework described above shows Congress and HHS do not limit reporting to Defendants definition of "handling" a vaccine. Defendants' narrow interpretation would defeat the legislative purpose to provide an early warning system for vaccine safety, comprehensive monitoring of outcomes, and public health data collection for agency analysis. Defendants confuse two distinct concepts: 1) being a "vaccination provider" eligible to participate in the program and 2) the scope of the organization's obligations once enrolled. Nothing in the EUA definition of "vaccination provider" limits the scope of reporting obligations. In fact, Defendants developed systems-level handling described in its COVID-19 Vaccine Clinic Playbook (Playbook) (Doc 34-25). That document shows Defendants had comprehensive system-wide procedures for implementing the vaccination program including includes organizational systems, policies, record-keeping, and adverse event monitoring. Id *sic passim*.

The existence of the Defendants COVID-19 Vaccine Clinic Playbook shows Defendants developed internal guidance and procedures for implementing the COVID-19 vaccination program, including guidance on adverse event reporting to VAERS so they could be paid. Id. Defendants knew of and acknowledged the requirement to report certain adverse events to VAERS, as the Playbook references this obligation. Id, p. 5. The Playbook's guidance on VAERS reporting does not align with Provider Agreement and federal regulations requirements. The 15-

minute post-vaccination monitoring period mentioned in the Playbook does not come from the EUA or Provider Agreement and could not cover the requirement to report a "congenital anomaly/birth defect" and other conditions which cannot manifest during vaccine administration. Doc. 34, ¶ 36.

Short-term monitoring should not be conflated with the comprehensive adverse event reporting requirements of the Provider Agreement and federal regulations. Defendants' staff understood there were reporting obligations beyond 15 minutes. For example, Dr. Notebaert emailed Conrad about people presenting with post vaccine complaints and the need to screen them. Doc. 34-5. The Playbook's limited guidance on VAERS reporting is evidence Defendants were not complying with or enforcing broader reporting requirements.

Defendants have argued that they only had to report a narrow subset of serious adverse events that occurred within 15 minutes of vaccine administration at the clinic site. But that interpretation simply doesn't square with the Agreement's plain ter

The Provider Agreement explicitly refers to the "Organization" as the responsible party, not just the person who injects the product. The certification states "all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine." Doc. 34-24. This organizational scope suggests "handling" extends beyond physical administration of a shot to the full spectrum of vaccine-related care. The Provider Agreement expands this duty by requiring healthcare providers administering the Covid-19 vaccines to report "moderate and severe" adverse events to VAERS. Doc. 34 ¶ 40; Doc 34-24. This requirement is explicitly labeled as a "material condition of payment." Id. In an express false certification claim, the claim itself "falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a

prerequisite to payment." *United States ex rel. Forcier v. Computer Scis. Corp*., 183 F. Supp. 3d 510, 522--23 (S.D.N.Y. 2016), citing *Mikes*, 274 F.3d at 698.

In *U.S. ex rel. Ellis v. Sheikh*, 583 F. Supp. 2d 434 (W.D.N.Y. 2008), the Western District of New York denied a False Claims Act defendant's motion to dismiss based on allegations of billing for medically unnecessary services. The court found the relator's complaint met the standards for notice and particularity because the plaintiff described the fraud in detail along with examples showing defendants' pattern of fraudulent activity. Id at 438. Similarly, Relator Conrad's FAC sufficiently alleges defendants knowingly refused to meet their obligations to report adverse events following vaccination to VAERS. She provided specific examples of non-compliance showing defendants were aware of their obligations yet chose not to fulfill them.

The Provider Agreement is a certification Defendants understand and acknowledge the materiality of the reporting requirements first established by the 1986 Act and the conditions of program participation under the EUA statute. By signing the agreement, defendants affirm adherence to these requirements and recognize that each claim for payment under the program is subject to False Claims Act liability for false certification of compliance. This agreement strengthens the elements of knowledge and materiality required for an FCA claim. These factors present a compelling case sufficient to overcome a motion to dismiss, justifying the opportunity for further factual development through the discovery process. Defendants' interpretations would create an absurd result where organizations could evade reporting requirements simply by separating vaccine administration from patient care. This directly contradicts the public health purposes of VAERS system and Provider Agreement.

3. Relator pleaded sufficient facts to show Defendants are liable for false implied certification of compliance with reporting requirements

An implied certification theory provides for liability where the claim for payment "makes specific representations about the goods or services provided" and the "defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 105 (2d Cir. 2021), citing *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 190, 136 S. Ct. 1989, 2001, 195 L. Ed. 2d 348 (2016) ("Escobar"). "A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." Id. at 1996 (emphasis added).

As demonstrated above, relator alleges sufficient facts to establish that defendants are liable for making claims of payment that were legally false, based upon the express and implied certifications that, as a vaccine provider, it complied with its VAERS reporting requirements. *See* Doc. 34 ¶¶102-109.

4. Defendants' contentions regarding clinical judgment to ignore VAERS reporting obligations on the basis of "causation" merely affirm their knowing misconduct

Contrary to defendants' assertions, providers may not determine if an adverse event following vaccination is reportable based on "clinical judgment" of causality. This assertion recklessly disregards their reporting obligations and undermines the purpose and function of VAERS as an early warning mechanism to detect potential safety signals associated with vaccines. If providers only reported events they deemed causally related to vaccination, it would undermine VAERS' effectiveness. The system relies on comprehensive reporting of all qualifying adverse events, despite the provider's opinion on causation, to allow for proper statistical analysis and

pattern recognition by public health experts. The VAERS guidance Defendants cite explicitly states that serious adverse events must be reported "regardless of causality." Even for non-serious events, Defendants acknowledge in their exhibit that providers are "encouraged to report any clinically significant adverse event, even if it is uncertain whether the vaccine caused the event." Doc 38-1, p. 6.

For example, defendants argue that "RRH investigated Relator's claims that certain patients required VAERS reports but reached a different medical opinion as to whether those patients' conditions triggered any reporting obligation." This disregards and interferes with Conrad's independent legal obligation, as a healthcare provider, to report adverse events. Regardless, Relator has provided several adverse reaction examples that qualify as either a serious or moderate adverse event within days of vaccine administration--a standard recognized under Federal Law. See 42 U.S.C. § 300aa-25.

Reporting requirements under the EUA were expanded reflecting the emergency nature of the COVID-19 vaccine rollout. The EUA emphasized VAERS as "early-warning system" and required monitoring due to novel nature of Covid-19 vaccines. It also broadened the definition of serious adverse events including hospitalization for Covid-19. Doc. 34 ¶ 28

The Provider Agreement, to which Defendants agreed, says nothing about clinical judgment in determining what to report to VAERS. But the plain language of the Provider Agreement reads, "Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS)." See Doc. 34-24, p 3. Further, it states this is a material condition of payment. Id.

There remains the question of whether "RRH investigated Relator's claims that certain patients required VAERS reports but reached a different medical opinion as to whether those

patients' conditions triggered any reporting obligation" and that only adverse events in the "vaccine clinic" should be reported. Doc. 38, p. 26. Defendants cite no authority for the proposition that clinical judgment can override mandatory reporting requirements.

At minimum, patient S.C., who tragically died 48 hours after vaccination, should have been reported to VAERS, and defendants' failure to report this patient violates the Provider Agreement. See Doc. 34, ¶ 87. Most of the listed required reporting events do not include medical judgment or room for disagreements between providers. Death and post-vaccine hospitalization must be reported and defendants knew it. Doc 38-1, p.6.

Defendants' argument relies on an unsupported hypothetical scenario. They presume, without factual basis, that for each of the 170 patients known to Relator whose adverse events went unreported, the treating providers made individual, considered decisions based on their medical judgment not to report to VAERS. This presumption is unsupported by the facts in the Amended Complaint and contradicts Relator's detailed allegations of systematic suppression of VAERS reporting by hospital leadership.

As explained above, under the clear terms of the regulations establishing the VAERS reporting system, medical providers, especially vaccine providers, may not exercise "clinical judgment" to determine not to report an adverse event following vaccination. Defendants argue providers can use clinical judgment to decide what to report to VAERS. This is wrong because the Provider Agreement and EUA requirements mandate reporting "regardless of causality" (Doc 38-1, p.6).

Even if providers could use their own medical judgment to determine reportability, there is no allegation such judgment was exercised in the examples provided by Conrad. Her allegations

suggest the opposite: that providers were discouraged or prevented from reporting adverse events, despite their medical opinions.

Finally, even if defendants' reporting requirements turned on exercising clinical or medical judgment by the providers, Relator's allegations show falsities in the failure to report. False statements of medical opinions are actionable under the False Claims Act. For example, the Third Circuit held that a hospice claim to Medicare may be legally false when based on a false medical opinion of the certifying physician, and that this falsity may be proven through expert testimony. *United States ex rel. Druding v. Care Alts*., 952 F.3d 89 (3d Cir. 2020), cert. denied, 141 S. Ct. 1371 (2021). The court held that "falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." *Id*., at 97. "[M]edical opinions may be 'false' and an expert's testimony challenging a physician's medical opinion can be appropriate evidence for the jury to consider on the question of falsity." *Id*., at 98.

This follows the rule in the Ninth Circuit, as applied to clinical judgments and certifications of "medically necessary." "A physician's certification . . . can be false or fraudulent for the same reasons any opinion can be false or fraudulent. These reasons include if the opinion is not honestly held, or if it implies the existence of facts . . . that do not exist." *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc*., 953 F.3d 1108, 1119 (9th Cir. 2020). See also *United States ex rel. Polukoff v. St. Mark's Hosp*., 895 F.3d 730, 742-46 (10th Cir. 2018) ("It is possible for a medical judgment to be 'false or fraudulent'").

Even under the Eleventh Circuit's opinion in *United States v. AseraCare, Inc*., 938 F.3d 1278 (11th Cir. 2019), Relator's allegations are enough to establish falsity. There, the Eleventh Circuit held that "objective falsity" is required under the Act. See *AseraCat at 1298*. But, even

under *AseraCare*, a clinical opinion may be objectively false if the physician fails to review medical records, to become familiar with a patient's condition, or to subjectively believe the patient was terminally ill; or when no reasonable physician could have concluded the patient was terminally ill given the relevant records. *AseraCare,* 938 F.3d at 1297.

Here, Relator sufficiently alleges the providers did not exercise any judgment or opine on causation. Instead, Defendants made sure providers did not report adverse events. Defendants' unsupported interpretation would undermine VAERS as an early warning system designed to detect potential safety signals through comprehensive data collection and expert analysis. Clinical judgment about causation comes after reporting, not before.

5. Relator's allegations show Defendants systematically failed to report many qualifying adverse events to VAERS violating their legal obligations.

Relator offers specific examples of patients who experienced serious adverse events shortly after vaccination, such as patient S.C. who died 48 hours after receiving the vaccine, patient E.F. who presented to the ER with sudden shortness of breath and fatigue one day after receiving the vaccine, S.B. who experienced syncope, convulsions, fevers, chills and myalgias one day after receiving the vaccine, and J.F. who presented to the E.R. three days after vaccination with arm pain and induration of the injected arm. Doc 34, ¶ 91. There is no reasonable dispute at this stage that Relator adequately alleged these patients should have been reported to VAERS considering that the guidance defendants use states that serious adverse events must be reported "regardless of causality." See Peacock Declaration, Doc. 38, p. 6. A patient who dies within 48 hours of receiving the vaccine must be reported to VAERS. See Doc. 34, ¶ 36.

Conrad has provided concrete evidence in her FAC that Defendants failed to report required adverse events to VAERS. She obtained and attached redacted vaccine cards for three patients who received vaccines at RRH (although Conrad does not know which RRH facility) and

subsequently experienced symptoms requiring VAERS reporting, including shortness of breath, syncope, and convulsions. (Doc 34. ¶ 91 & Doc 34-26).

These three patients were admitted to RRH and appear as M.D. (#78), N.M. (#25), and C.M. (#86) on Conrad's list of 170 cases she tried but was stopped from reporting to VAERS. Doc. 34, ¶ 92. While she only has vaccine cards for a small number of the 170 listed patients, these three cases demonstrate that Defendants had the necessary information to file VAERS reports but failed to do so. This documented evidence of noncompliance is sufficient to defeat a motion to dismiss.

The FAC identifies, by initials, other patients whose post-vaccination adverse events Defendants failed to report. Doc. 34 ¶ 92. These patients suffered an array of VAERS-reportable symptoms, from cardiac issues and blood clots to neurological events and autoimmune flare-ups. Id. By cataloguing these case examples in such detail, Relator has bolstered her underreporting allegations. This is not a generalized grievance, but a claim about real patients and real failures to abide by reporting obligations.

Relator's examples show the critical public health interests at stake when vaccine adverse events go unreported. Contrary to the Defendants' apparent belief, VAERS reporting is not a formality - it is an essential tool to quickly identify potential safety issues. Every time the Defendants neglected to file a required report, they deprived government regulators and the public of important safety data. Doc. 34 ¶ 23. Relator's allegations, if confirmed, would show that the Defendants defrauded the government and put the public at risk by concealing information that could have revealed vaccine dangers. The FAC, through patient-specific examples, leaves no doubt these reporting failures had real consequences.

As an insider with access to patient files, Conrad could identify adverse events the Defendants ignored. While Conrad may not have worked in the RRH vaccine clinics, her level of access and her communications with clinic staff gave her personal knowledge of underreporting to meet the Rule 9(b) standard. Doc. 34, ¶¶ 56, 57, 81, 93. She lost access when she was fired.

The FAC's factual allegations, exemplified by the vaccine card records and the long list of unreported patients with adverse events, support Relator's claim that Defendants systematically flouted reporting duties. Defendants argue there is no duty to report every adverse event to VAERS *ad infinitum*, which may be true, but they cannot succeed on a motion to dismiss by ignoring actual examples in the FAC. Relator has stated a claim at this stage and should be allowed to move forward with discovery.

To get around the clear examples Relator offers in the FAC, Defendants argue the requirement to report adverse events "following" vaccination limits the reporting requirement only to "temporal proximity to receiving the vaccine. Defendants' Motion, Doc. 38, p. 7. Defendants' contention is disproven by the defined adverse events spelled out even in the reporting guidance Defendants offer. Beginning with a "congenital anomaly/birth defect," it is unreasonable to presume that this adverse event must be reported only when a pregnant woman, in labor at the hospital, receives the Covid-19 vaccine and then gives birth to a baby with a congenital anomaly or birth defect. See Peacock Declaration, Doc. 38-1, p. 6. Similarly, a "persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions" cannot reasonably be measured only during the time a patient remains at the hospital following vaccination, especially not during the 15 minutes Defendants discuss in their guidance on vaccine administration. Id. These listed adverse events anticipate a longer period after vaccination than the time a vaccine recipient is at the vaccine clinic.

6. Scienter.

The FAC alleges multiple communications and meetings with Hospital management discussing their obligations to report to VAERS, including specific patients that Relator alleged should have been reported to VAERS. Doc. 34, ¶¶ 110-116. Defendants knowingly submitted false claims through a coordinated organizational strategy to suppress VAERS reporting while continuing to certify compliance to obtain federal payments.

This knowing conduct occurred at multiple levels within the organization. At the leadership level, RRH's CMO Dr. Gellasch explicitly acknowledged on May 24, 2021 that "we must report to VAERS per guidance," demonstrating actual knowledge of the obligation. Id., ¶ 110. Yet rather than ensure compliance, leadership actively undermined reporting through systematic actions - cutting off communication between providers discussing adverse events, ordering Relator to "dial it back," and retaliating against staff who attempted to report. Id., ¶ 112. This suppression culminated in explicit concealment, such as removing vaccine information from patient S.C.'s death certificate and medical records. Id., ¶ 116.

Defendants' scienter is further shown through both deliberate ignorance and reckless disregard. Despite the Provider Agreement requiring the CEO and CMO to certify that "all relevant officers, directors, employees and agents" understood reporting obligations, President Dan Ireland explicitly stated "it is not the organization's duty to educate providers" - directly contradicting their certification. Id., ¶ 114. Meanwhile, Defendants prioritized maximizing vaccination rates and federal payments over safety monitoring, maintaining no effective system for VAERS reporting even as they continued submitting claims certifying compliance.

This comprehensive pattern of behavior - from explicit acknowledgment of the duty, to active suppression of reporting, to failure to implement an effective compliance system -

demonstrates Defendants knowingly submitted false claims under the FCA's definition of knowledge.

7. Materiality

Conrad's allegations lead to a strong inference that specific claims for payment were presented to, and paid by, the United States pursuant to the fraudulent scheme. Her allegations show VAERS reporting was material to payment and Defendants knew it. The Provider Agreement made VAERS reporting a material condition of payment, and Defendants responded to Relator's concerns about underreporting not by correcting non-compliance, but by concealing it--including altering patient S.C.'s medical records to remove vaccine information, directing staff to suppress reporting, and retaliating against employees attempting to report, all while continuing to submit claims for payment. Doc. 34, ¶¶ 117-119.

The materiality of VAERS reporting is confirmed by its inclusion as a condition in the EUA statutory framework and the Provider Agreement. Each claim for payment, regardless of whether the patient was injured, includes the certification that adverse events are being reported to VAERS. No government agency has declared such reporting optional or permitted systematic non-reporting. Defendants' aggressive efforts to hide their non-compliance claiming $40 payments for tens of thousands of vaccine administrations shows they understood disclosure of systematic non-compliance would threaten their continued receipt of federal funds.

8. Relator pleads particular facts to meet Rule 9b requirements.

In the FAC, Relator pleaded with particularity the Defendants' scheme to defraud the United States by claiming payments for vaccine administration that were legally false. Her allegations include the who, what, where, when, and how of Defendants' knowing and conscious disregard of their VAERS reporting obligations. Relator pleaded specific examples of adverse events not reported, including a chart showing 170 instances of non-compliance with patient

initials and dates of service. Relator also pleaded sufficient indicia leading to a strong inference that specific claims for payment were presented to, and paid by, the United States. These allegations are enough to satisfy Rule 9(b). See *United States ex rel. Chorches v. Am. Med. Response, Inc.,* 865 F.3d 71, 89-93 (2d Cir. 2017).

In *Chorches*, the Second Circuit adopted the approach taken by sister circuits finding Rule 9(b) satisfied when the relator alleges "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." 865 F.3d 71, at 89-93 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). Importantly, in "applying Rule 9(b) to the submission of false claims under subsections 3729(b)(2)(A) and (B) of the FCA," the Court in *Chorches* "decline[d] to require that every qui tam complaint allege on personal knowledge specific identified false invoices submitted to the government." 865 F.3d at 86. Indeed, the Second Circuit held that to require a relator to have personal knowledge of both the fraudulent conduct and claim submissions would effectively nullify the qui tam provisions of the False Claims Act, as neither the "line-worker" like Conrad who witnesses the fraud, nor the "accountants who submit the claims" would ever meet Rule 9(b) standards. Id. What is important is that the allegations of fraudulent conduct be sufficient to meet the purposes of the rule: to provide "fair notice," to "safeguard" reputations from "improvident charges" and to protect against "strike suits." *Id*., at 86-89.

Under this approach, Relator -- who worked as a provider, not as an individual in the billing department -- need not allege facts of specific invoices presented by Defendants for payment in connection with vaccine doses they administer. Before being fired, Conrad confirmed patients' Covid-19 vaccination status through the New York State Immunization Information System (NYSIIS) system and the Defendants' electronic records system called EPIC. Instead, so long as

Relator pleaded the fraudulent scheme with enough particularity, she satisfies Rule 9(b) regarding the "claim" element by "making plausible allegations creating a strong inference that specific false claims were submitted to the government." *Chorches*, 865 F.3d at 86.

Here, Conrad alleged Defendants entered into Provider Agreements with the United States and provided Covid-19 Vaccines to thousands of its patients. Defendants Playbook shows they participate in the federal Covid-19 Vaccination Program. Doc. 34, ¶ 96. She also alleged Defendants presented false or fraudulent claims for payment pursuant to the fraudulent scheme. Id, ¶ 97. Indeed, Relator alleged that information regarding the specific invoices is within the exclusive control of the Hospital Defendants. Doc. 34, ¶¶97, 108. Relator's allegations are enough to survive defendants' motion to dismiss.

9. Relator pleaded sufficient facts to establish fraud in the inducement.

Relator Conrad sufficiently pleaded fraudulent inducement by alleging Defendants entered into the CDC COVID-19 Vaccination Program Provider Agreement with no intention of complying with its VAERS reporting obligations. Specifically, the FAC alleges RRH's President Dan Ireland admitted "it is not the organization's duty to educate providers about the VAERS system and what to report, it is the providers duty to educate themselves on this." Doc 34, ¶81. This statement directly contradicted the Provider Agreement which required the CMO and CEO to certify that "all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine understand and will comply with the agreement requirements." Doc. 34, ¶41; Doc 34-24.

The FAC also details how Defendants systematically suppressed VAERS reporting from the outset by failing to educate staff about reporting requirements (Doc. 34 ¶¶ 57-58), cutting off communication between providers trying to ensure proper reporting (Doc. 34 ¶ 56), auditing and trying to restrict Conrad's reporting (Doc. 34 ¶¶ 63-72), and labeling people who tried to report as

"anti-vaxxer[s]" (Doc. 34 ¶ 70). These allegations show Defendants fraudulently induced payment by Covid-19 Vaccination Program by certifying compliance with safety tracking requirements without intending to implement comprehensive adverse event reporting.

10. Relator adequately pleaded conspiracy.

In Count III, Relator pleads that defendants, individually and collectively, conspired to violate 31 U.S.C. § 3729(a)(1)(C). ECF 1, ¶86. In the FAC, Relator alleges details of the unlawful purpose of the conspiracy and the resulting false clai Doc 34, ¶¶ 120-122.

Defendants contend they are not subject to liability for intra-corporate conspiracies, under a doctrine developed in the anti-trust arena not understood to apply to the False Claims Act. See *United States ex rel. Millin v. Krause*, 2018 WL 1885672 (D.S.D., 2018). It is hard to conceive of the impact of this doctrine in a case like this one, where relator alleges that defendants violated the FCA by reaching agreements with each other, and with providers with independent obligations to report to VAERS. Such agreements caused false claims, and the doctrine would create exceptions to liability in the circumstances where defendants took the unlawful actions set forth in the FAC.

Here, the Court need not determine whether the doctrine bars Relator's conspiracy claim, as the allegations show each defendant and healthcare providers had their own "independent personal stake in achieving" the illegal goal. See *Greenville Pub. Co. v. Daily Reflector, Inc*., 496 F.2d 391, 399 (4th Cir. 1974); *Eplus Tech., Inc. v. Aboud*, 313 F.3d 166, 179-80 (4th Cir. 2002); *United States ex rel. Lowery v. All Medicines, Inc*., 2021 WL 1405960 (E.D.N.C., 2021). Relator's allegations do not show a "ministerial act" by the hospital or the providers to carry out their corporate overseers' plans. See *Webb v. Cnty. of El Dorado*, 2016 WL 4001922 (E.D.Cal., 2016). To the contrary, relator alleges that each provider, including herself, had an independent duty to comply with VAERS, an independent financial interest in maintaining high vaccination rates, and an individual motive to suppress information about the public health damage caused by the

vaccines they recommended and/or administered. Each defendant had a stake in meeting the illegal goal. The intra-corporate conspiracy doctrine provides no defense.

11. Relator adequately pleaded reverse false claims

Under 31 U.S.C. § 3729(a)(1)(G), a defendant violates the False Claims Act if it "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money," or "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money" to the United States. In Count IV, Relator alleges the Defendants violated the Act by knowingly receiving and retaining Provider payments to which they were not entitled to avoid their obligation to pay those funds back to the United States.

The obligation to return money wrongfully paid in non-compliance with the Provider Agreement is not dependent of the Organization's liability under the False Claims Act. As such, the obligation is independent of the Act and properly forms the basis under the reverse false claims theory. See, e.g., *United States ex rel. Martinez v. KPC Healthcare Inc*., 2017 WL 10439030, at *6 (C.D.Cal., 2017) ("In 2010, however, Congress established an independent legal duty of Medicare payment recipients to 'report and return' an overpayment within sixty days 'after the date on which the overpayment was identified'"); *United States v. Sutter Health*, 2021 WL 9182522, at *13 (N.D.Cal., 2021) (independent obligations to return overpayments under the anti-kickback statute and Stark law provide bases for reverse false claims).

C. <u>RELATOR STATED A PLAUSIBLE RETALIATION CLAIM</u>

1. Standard of review

The particularity requirement of Rule 9(b) does not apply to retaliation claims under the FCA. *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc*., 865 F.3d 71, 95 (2d Cir. 2017) citing *Weslowski v. Zugibe*, 626 Fed.Appx. 20, 20 (2d Cir. 2015) (in

reviewing the Rule 12(b)(6) dismissal of a § 3730(h) claim, stating, without mentioning Rule 9(b), that the complaint is to be construed "liberally" under *Twombly* and *Iqbal*); accord, *Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 433 (4th Cir. 2015) (stating that FCA retaliation claims "need pass only [Federal Rule of Civil Procedure] 8(a)'s relatively low notice-pleadings muster—in contrast to Rule 9(b)'s specificity requirements"); *Mendiondo v. Centinela Hosp. Med. Ctr*., 521 F.3d 1097, 1103 (9th Cir. 2008); *U.S. ex rel. Williams v. Martin-Baker Aircraft Co*., 389 F.3d 1251, 1259 (D.C. Cir. 2004). Instead, such claims are reviewed under the plausibility standard of Rule 12(b)(6). *United States ex rel. Schwartz v. Document Reprocessors of New York, Inc*., 692 F. Supp. 3d 71, 78 (W.D.N.Y. 2023).

Under that standard, a court must consider the motion by "accepting all factual allegations as true and drawing all reasonable inferences in favor of the plaintiff." *Trs. of Upstate N.Y. Eng'rs Pension Fund v. Ivy Asset Mgmt*., 843 F.3d 561, 566 (2d Cir. 2016). To withstand dismissal, a claimant must set forth "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Turkmen v. Ashcroft*, 589 F.3d 542, 546 (2d Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)).

2. The FCA's anti-retaliation provision

The FCA's anti-retaliation provision provides:

> [a]ny employee ... shall be entitled to all relief necessary to make that employee ... whole, if that employee ... is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee ... in furtherance of an action under this section or other efforts to stop 1 or more violations of [the FCA]. 31 U.S.C. § 3730(h)(1).

To state a claim of retaliation, a plaintiff must allege: (1) the employee "engaged in activity protected under the statute," (2) "the employer was aware of such activity," and (3) "the employer took adverse action against" the employee because of the protected activity. *Pilat v. Amedisys, Inc*., No. 23-566, 2024 WL 177990, at *1 (2d Cir. Jan. 17, 2024), citing *Chorches*, supra, 865 F.3d 71, 95.

The retaliatory discharge must occur because of the protected conduct. *United States v. N. Adult Daily Health Care Ctr.,* 205 F. Supp. 3d 276, 299 (E.D.N.Y. 2 See Doc. 34 at pp. 89-90, Ex. 24 (stating the agreement is "between Organization and CDC" and "Organization agrees that it will adhere to the following requirements: [...]"). Further, Relator's FAC pleaded an ongoing and knowing refusal to report adverse events to VAERS, spanning multiple members of Defendants' organizations who rely on a purported "system" which led them to determine that adverse events should not be reported as required by federal regulations and the Provider Agreement.

Taking the FAC's well-pleaded allegations as true, Relator has satisfied each element. Over several months Relator repeatedly sounded the alarm to management about illegal, unethical, and knowing failures to report adverse events to VAERS. See, Doc. 34, ¶¶ 65-66, 68-69, 75-78; Docs. 34-12, 34-16, 34-18. Relator was told to "dial it back," that she was overreporting to VAERS, and to only report her own patients to VAERS. Doc. 34, ¶¶ 68, 74. Defendants threatened a complaint against Relator's professional license due to her VAERS reporting activities and for allegedly spreading vaccine misinformation. *Id*., ¶ 86. Relator went public on The Highwire, which aired September 17, 2021, discussing the suppression of vaccine side effects reporting to VAERS. Id., ¶ 88. On October 6, 2021, Conrad was interrogated by RRH's HR Director about her media statements and was then escorted to her workstation on the main medical floor, humiliated before

her peers in the middle of her 12-hour shift, asked to leave the hospital immediately, and was observed closely by HR staff as she was walked out. Id., ¶ 90.

3. Relator engaged in protected activity

Under the statute, relators engage in protected activity if they engage in "efforts to stop 1 or more violations of" the FCA. *Pilat*, supra, citing 31 U.S.C. § 3730(h)(1). Such efforts can include both complaining internally to supervisors about suspected fraudulent practices and refusing to engage in such practices. *Pilat*, supra, citing *Chorches*, 865 F.3d at 97–98 (noting, "at best, a hair's-breadth distinction between complaining internally that a practice is illegal under the FCA and advising a supervisor of one's refusal to engage in that illegal practice" and rejecting "[a]ny line-drawing between the two, so as to qualify one but not the other as protected activity under § 3730(h)").

A retaliation claim can be stated "so long as the employee was engaged in efforts to stop an FCA violation, even if the employee's actions were not necessarily in furtherance of an FCA claim." *United States v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 298 (E.D.N.Y. 2016). A party need not succeed on the underlying FCA claim to show retaliation, but she "must demonstrate that [s]he had been investigating matters that were calculated, or reasonably could have led, to a viable FCA action." *Schwartz*, 692 F. Supp. 3d 71, 81, citing *N. Adult Daily*, 205 F. Supp. 3d at 298 (original alteration and quotation omitted).

Several decisions from the Second Circuit and courts within the Second Circuit show internal complaints about fraudulent activity, even with no specific mention of the FCA or specific use of the word "fraud," are protected activity for FCA retaliation purposes. In *Pilat v. Amedisys, Inc.*, No. 23-566, 2024 WL 177990 (2d Cir. Jan. 17, 2024), the Second Circuit reversed the district court's dismissal of the relators' retaliation claims, and found relators engaged in protected activity.

In *Pilat*, relators alleged defendant, a home health and hospice care company, certified unqualified patients for home health care, provided unnecessary and improper treatment, falsified time records, and manipulated patient records.

In that case, relators stated retaliation claims too. The Second Circuit upheld these claims, finding one relator's refusal to recertify a Medicare patient a third time and calling the practice unethical protected activity. Though the relator "voiced concerns about 'unethical' behavior, as opposed to 'illegal' behavior, his comments support the inference that he was attempting to prevent Amedisys from providing, and overbilling for, unneeded treatment." *Id*., at * 2.

The Court found the second relator's complaints to management about too high a volume of patients was also protected activity, since the complaint alleged the services were being billed in full but could not be fully performed given the high patient volume. Likewise, the Court determined efforts constituting protected activity, "can include both complaining internally to supervisors about suspected fraudulent practices and refusing to engage in such practices." *Id*.

Here, Conrad complained internally to supervisors about the suspected fraudulent practice of failing to report adverse events to VAERS, explicitly calling such practices illegal. She also refused to engage in this activity and, against the demand from her supervisors that she only make reports for her own patients, she took it on herself to report adverse events suffered by the patients of other providers.

In *United States v. Applied Memetics, LLC*, No. 5:21-CV-270, 2024 WL 5316335 (D. Vt. Dec. 4, 2024), the court found on summary judgment the relator's conduct was protected activity where the relator "repeatedly expressed concerns about the falsehoods that Defendants included in their bids, their 'bait-and-switch' tactics, and the impacts of staffing projects with underqualified employees." *Id*., at *21. The defendants contended these complaints were not protected actions

because they showed no recognition by the relator, at the time, that the issues were FCA violations, and they did not show an effort by the relator to stop any perceived FCA violations. *Id*. Citing *Pilat*, supra, and *United States ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806, 2013 WL 1346022, at *9 (E.D.N.Y. Apr. 3, 2013) (holding a plaintiff need not even be aware that her investigation could lead to an FCA claim to show she has engaged in a protected activity), the court noted the relator "may not have expressed those concerns as allegations of fraud, but she was raising concerns about fraud nonetheless." *Applied Memetics, LLC*, supra, at *21.

In *United States v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, (E.D.N.Y. 2016), relators filed a retaliation claim under the FCA after adverse employment actions. One relator was forced to resign due to intolerable working conditions, while the other was demoted and later fired. These actions came after they raised concerns about: (1) discriminatory treatment of African American and Latino program participants, (2) unsanitary food handling practices, and (3) inadequate training of food service personnel. Relators claimed these issues violated the respondent's certifications of compliance with Title VI and Department of Health regulations. *Id*., at 296-97. The court denied defendant's motion to dismiss stating "Without fact discovery, the Court cannot conclude that Lee's and Luckie's internal reporting to Northern Adult management, and management's response, do not constitute paradigmatic whistleblowing and retaliation under the FCA and NYFCA." *Id*., at 299.

Like the defendant in *Applied Memetic*, and the Defendants here, the defendant in *N. Adult Daily* argued for dismissal because relators' complaints did not put them on notice of relators' intent to file a *qui tam* lawsuit. The court found this misstated the law, and stated, "Because Relators claim that Defendants violated the FCA by impliedly certifying compliance with Title VI and DOH regulations, they have adequately pled that their complaints to management about

violations of those rules and regulations were "in furtherance of ... efforts to stop 1 or more violations of [section 3730(h)(1)]," and constitute protected conduct." *Id*., at 299-300.

In *Bernstein v. Silverman*, No. 5:20-CV-630 (MAD/CFH), 2024 WL 3595621, the relator alleged false attestation of reading, interpreting, and evaluating the results of ultrasound and fetal nonstress tests ordered for patients and billing for them. The relator reported this behavior to the doctor accused of the fraud, who was the relator's supervisor and to institutional leaders, and encouraged them to take corrective action. The court found, "Relator's allegations are similar to those in *Pilat*. Relator has alleged that she expressed concern to her supervisors about Dr. Silverman's practices, which she has also alleged were fraudulent." *Bernstein*, 2024 WL 3595621, at *26.

In *Conte v. Kingston NH Operations LLC*, 585 F. Supp. 3d 218 (N.D.N.Y. 2022), the sole case Defendants cite in arguing relator did not engage in protected activity, the court found an employee's activity not protected where the employee complained about the employer's failure to follow a state-issued mask mandate. The court found relator's complaints expressed her concern for the health and safety of employees and residents and were not calculated to, nor could reasonably lead to discovery potential violations of the False Claims Act. Unlike *Conte*, here Relator reported adverse events to VAERS and repeatedly complained to her supervisors that VAERS reports needed to be made for several patients with known adverse events to comply with federal regulations and the guidance of federal health agencies. The reasoning of *Conte* does not apply here because adverse event reporting regulations and the Provider Agreement are federal requirements for reimbursement under the Covid-19 Vaccination Program and not a state mandate. Further, Conrad's concerns were not merely for patient and staff safety. These patients presented

to Defendants' hospital with adverse events that Conrad determined met the threshold to report to VAERS under the Provider Agreement.

Under the reasoning of *Pilat*, *Applied Memetics*, *N. Adult Daily*, and *Bernstein*, Relator has plausibly alleged protected activity to support a claim for FCA retaliation under 31 U.S.C. § 3730(h). On May 24, 2021, Relator emailed Defendant Hospitals management stating, "We as health care providers are required **by law** to report these cases." Doc. 34, ¶ 65; Doc. 34-12, p. 5. On May 25, 2021, Relator exchanged emails with Dr. Gellasch regarding patients needing VAERS reports, identifying seven patient deaths. Id., ¶ 66. The response Conrad received was that she needs to "dial it back." Id. When Relator again explained her concerns about underreporting and adverse events, she was called an anti-vaxxer and told to "tow the company line." Id., ¶¶ 68-71. She continued to report patients that should have been reported to VAERS including patient L.C. Id., ¶ 75. On May 31, 2021, Conrad emailed Dr. Gellasch information from the CDC website justifying why L.C. should be reported. Id. She requested the patient's VAERS case number for her records stating, "because now having knowledge of this case and not reporting it myself as I have been instructed to do by the system, puts me in a position to knowingly violate the law." Id; Doc. 34-16. To her knowledge, L.C. was not reported to VAERS. Id. In June of 2021, Conrad continued communications with Dr. Gellasch and Dr. Janes about more patients that needed to be reported to VAERS. Doc. 34, ¶¶ 76-78. In an email on June 25, 2021, Relator again reminded Dr. Gellash and Dr. Janes about what had to be reported under federal regulations. Doc.s 34-16; 34-18. Relator stated:

> Below again is what we are required as healthcare providers to report, it says nothing that it is up to interpretation. Inpatient hospitalization following covid 19 vaccination is considered a serious safety event as are cases of covid 19 following hospitalization or resulting in death. I am not over reporting or interpreting the VAERS guidance too broadly as suggested. It also states that providers are encouraged to report even if they don't think it may be due to the vaccine. This is

> the ethical thing to do. Why would the hospital not want to be transparent with the FDA and the community we serve? Each one of these VAERS reports represents a life possibly affected negatively from the vaccines and they deserve to have their reports made. We have 2 patients fully vaccinated who were hospitalized and treated for covid 19, one of which died. Id.

Conrad engaged in protected activity by alerting management to illegal and unethical practices of VAERS underreporting. She further engaged in protected activity by reporting adverse events to VAERS for other providers. Through these activities, she tried to stop one or more violations of the FCA. Thus, Defendant's argument fails, and Conrad has plausibly alleged she engaged in protected activity.

4. Defendants had notice of Relator's protected activity

Defendants do not argue they lacked notice of Relator's protected activity as alleged in the FAC. The FAC discusses and provides examples of communication between Conrad and management regarding VAERS underreporting along with many responses from management acknowledging, disagreeing with, threatening, and terminating Relator because of her protected activity. There is no path to try to argue Defendants were not on notice, and it is essentially conceded they had notice of Relator's protected activity.

5. Relator plausibly pleaded she was terminated because of her protected activity

The retaliatory discharge must occur *because of* the protected conduct. *United States v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 299 (E.D.N.Y. 2016) (internal citations omitted). "At the motion to dismiss stage, the temporal proximity of plaintiff's [protected conduct] ... is a sufficient basis to permit the claim to go forward." *Id*., citing *Garcia v. Aspira of New York, Inc.*, No. 07 CIV. 5600 PKC, 2011 WL 1458155, at *5 (S.D.N.Y. Apr. 13, 2011). Meeting the default "but-for" cause requirement is hardly onerous following the Supreme Court's decision in *Bostock v. Clayton Cty*., 590 U.S. 644, 656-667 (2020). There, the Supreme Court held that to meet

but-for causation in the employment setting, an employee must show protected activity was *a* "but-for" reason for the employer's intentional act, but she need not prove it was a "sole," "main," "primary" or even the "most important" reason for the adverse decision. In fact, there may be, and often are, multiple but-for reasons. It is irrelevant whether non-retaliatory factors also motivated the decision, even if other factors played a more important role. *Id*.

Applying proper standards, a relator alleging retaliation under the FCA has "a *minimal* burden of showing facts suggesting an inference of discriminatory motivation. See *United States v. Applied Memetics, LLC*, No. 5:21-CV-270, 2024 WL 5316335, at *23 (D. Vt. Dec. 4, 2024).

Defendants assert, "Relator does not allege any facts that show her alleged termination had anything to do with her concerns about VAERS underreporting." MTD, Doc. 38, at p. 32. A review of the facts alleged suggests Defendants' pivotal assertion cannot be serious. On September 22 and September 27, 2021, Conrad was interrogated by Dr. Gellasch and Dr. Janes about various "patient family/friend complaints" surrounding VAERS reporting of patients' vaccine injuries and threatened to report her to the New York State Society for Physician Assistants (NYSSPA) for spreading misinformation about the vaccines. Doc. 34, ¶ 86. Conrad made statements to the media about her concerns with vaccine side effects and underreporting to VAERS. Id., ¶¶ 88-89. Specifically, Conrad went public on The Highwire, which aired September 17, 2021, discussing the suppression of vaccine side effects reporting to VAERS. Id., ¶ 88. On October 6, 2021, Conrad was interrogated by RRH's HR Director about her media statements and later that day was escorted to her workstation on the main medical floor, humiliated before her peers in the middle of her 12-hour shift, asked to leave the hospital immediately, and was observed closely by HR staff as she was walked out. Id, ¶ 90. These facts as pled permit an inference that Conrad's termination had *at least something to do* with her concerns about VAERS underreporting.

As the Second Circuit has instructed, "[t]he question at the pleading stage is not whether there is a plausible alternative to the plaintiff's theory; the question is whether there are sufficient factual allegations to make the complaint's claim plausible." *Anderson News, L.L.C.* v. *Am. Media, Inc.*, 680 F.3d 162, 189 (2d Cir. 2012). The plausibility standard is lower than a probability standard, and there may therefore be more than one plausible interpretation of a defendant's words, gestures, or conduct. *Id*., at 189-90. Although an innocuous interpretation of a defendants' conduct may be plausible, that does not mean that a plaintiff's allegation that conduct was culpable is not also plausible. *Id*. Accordingly, "on a Rule 12(b)(6) motion it is not the province of the court to dismiss the complaint on the basis of the court's choice among plausible alternatives.... [T]he choice between or among plausible interpretations of the evidence will be a task for the factfinder." *Id.* at 190; *see also Confido Advisors, LLC* v. *USAA Real Est. Co.*, No. 17 Civ. 5632 (JFK), 2018 WL 4265900, at *5 (S.D.N.Y. Sept. 6, 2018) ("That two plausible inferences may be drawn from factual allegations is not a choice to be made by the Court on a Rule 12(b)(6) motion[.]").

Defendants argue Conrad was fired for an alternative reason--being noncompliant with the New York State healthcare vaccine mandate. Despite the unanswered question as to why Defendants assert the compliance date was October 7, 2021 rather than September 27, 2021, Defendants' argument raises and fails to answer critical questions. For example, were all non-compliant employees fired on October 6, 2021? Were those noncompliant employees escorted out of the building in the middle of their shifts on October 6, 2021? While Defendants' unpleaded alternative theory for Relator's termination cannot be weighed against Relator's plausibly alleged facts showing retaliation, Defendants' alleged behavior does not suggest that Relator was terminated in due course simply for noncompliance with the vaccine mandate. Further, discovery is needed to answer these important questions that Defendants' premature argument raises.

Moreover, under *Bostock*, even if – contrary to the facts alleged – Hospital Defendants had a non-retaliatory reason for terminating Conrad, such a reason would not negate the allegation or ultimate proof that *a* but-for reason of the termination was her efforts to stop a violation of the Act. *See Bostock*, 590 U.S. at 659 ("*It doesn't matter* if other factors besides" protected status "contributed to the decision") (emphasis supplied).

6. New York Labor Law retaliation claim

Defendants do not challenge Relator's claim on the pleadings under New York Labor Laws §§ 740 and 741. Instead, they ask the Court to decline supplemental jurisdiction over this claim *if* all federal claims are dismissed. While Relator asserts that all claims should survive Defendants' challenge, Relator asks that, if the Court dismisses the other claims, it retain jurisdiction over the state law claim as judicial economy supports keeping this case in this Court rather than refiling it in state court. Since the FAC was not otherwise challenged on this claim, Relator states no further.

7. The Court should exclude Exhibit D to the Declaration of James E. Peacock, Esq.

The Court should exclude Defendants' Exhibit D attached to the Declaration of James E. Peacock, Esq. See Doc. 38-1, Page 39-42. Relator's affidavit submitted in support of a separate and unrelated case is not a "docket sheet" as in *Mangiafico*. See Doc. 38, at p. 32, fn. 8. Further, the affidavit is not referenced in the FAC nor does the FAC rely heavily on its terms and effect, and it is not rendered integral to the FAC. See *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152–53 (2d Cir. 2002). In *Mangiafico v. Blumenthal*, 471 F.3d 391 (2d Cir. 2006), the Second Circuit found no error in relying on a docket sheet because "(1) docket sheets are public records of which the court could take judicial notice, *see Pani v. Empire Blue Cross Blue Shield,* 152 F.3d 67, 75 (2d Cir.1998), **and** (2) Mangiafico's complaint incorporated pleadings from the *Ziemba* action referred to in the docket sheet, *Chambers,* 282 F.3d at 153." *Mangiafico* at 398 (emphasis added).

Defendants omit the second part of the Court's reasoning and thereby tacitly admit Relator's affidavit is not incorporated or referenced in the FAC. Thus, if the Court is to consider it, then "the motion shall be treated as one for summary judgment and disposed of as provided in [Federal Rule of Civil Procedure] 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion...." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152–53 (2d Cir. 2002), citing Fed. R. Civ. P. 12(b). Under the standards, however, the Court should exclude Relator's affidavit, Doc. 38-1, Page 39-42.

III. CONCLUSION

Relator Conrad's FAC presents a detailed, compelling case that the Defendants systematically violated their VAERS reporting obligations under federal law and the COVID-19 Vaccination Program while falsely certifying compliance to keep the vaccine funds flowing. Her well-pleaded allegations describe a knowing scheme carried out at the highest levels of the organizations to discourage, restrict, and punish adverse event reporting in the name of maintaining public confidence and hitting vaccination targets. This interfered with providers, like Conrad, from meeting their independent professional obligations as set for in the VAERS program and in the Program Participation Agreement. If proven, this misconduct would be a serious breach of the Defendants' duties as a vaccine providers and would reveal a troubling effort to avoid accountability at the expense of patient safety and public health. It would frustrate the core purposes of the VAERS system - to promptly and accurately identify potential vaccine safety issues - and undermine the integrity of the COVID-19 Vaccination Program.

Relator Conrad has done what the False Claims Act empowers whistleblowers to do: expose fraud and hold wrongdoers to account. Her claims are grounded, specific, and deeply

concerning. Conrad deserves the opportunity, granted through the *qui tam* provisions of the Act, to pursue this action and hold Defendants accountable for their fraud and false claim.

Congress established that transparency and accountability matter profoundly in our vaccine safety system and in public health efforts more broadly. The Defendants had to report adverse events and help monitor these novel vaccines. Relator's allegations show they failed in that responsibility and knowingly concealed that failure from the government and the public.

The False Claims Act vindicates the public trust. When entities like these Defendants accept public funds, conditioned on compliance and transparency, the public has a right to have those conditions met. Whistleblowers like Relator Conrad are guardians of that right. The Court should allow her case to move forward and her voice to be heard.

Respectfully Submitted,

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Counsel for Relator

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on all parties that have appeared through the Court's electronic filing system on 1-31-2025.

/s/ Warner Mendenhall
Warner Mendenhall, 0070165